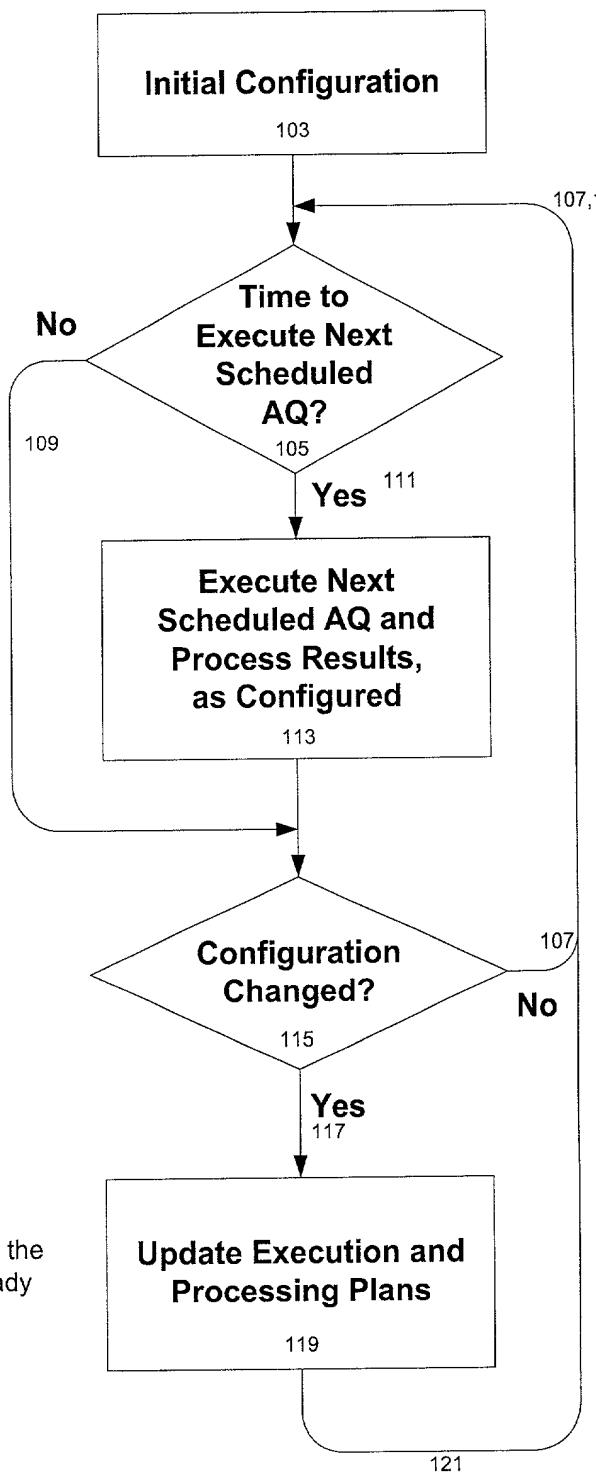


**103:** The Initial Configuration is used to define the execution and processing plans, including the following:

- Query (search / trigger criteria)
- Admin Scope
- Admin Schedule
- Admin Activity
- Admin Query

**104:** In this step the next scheduled Admin Query, is executed, querying the database, searching for records meeting the given Admin Query conditions, and processing all PRs in the Result Set.

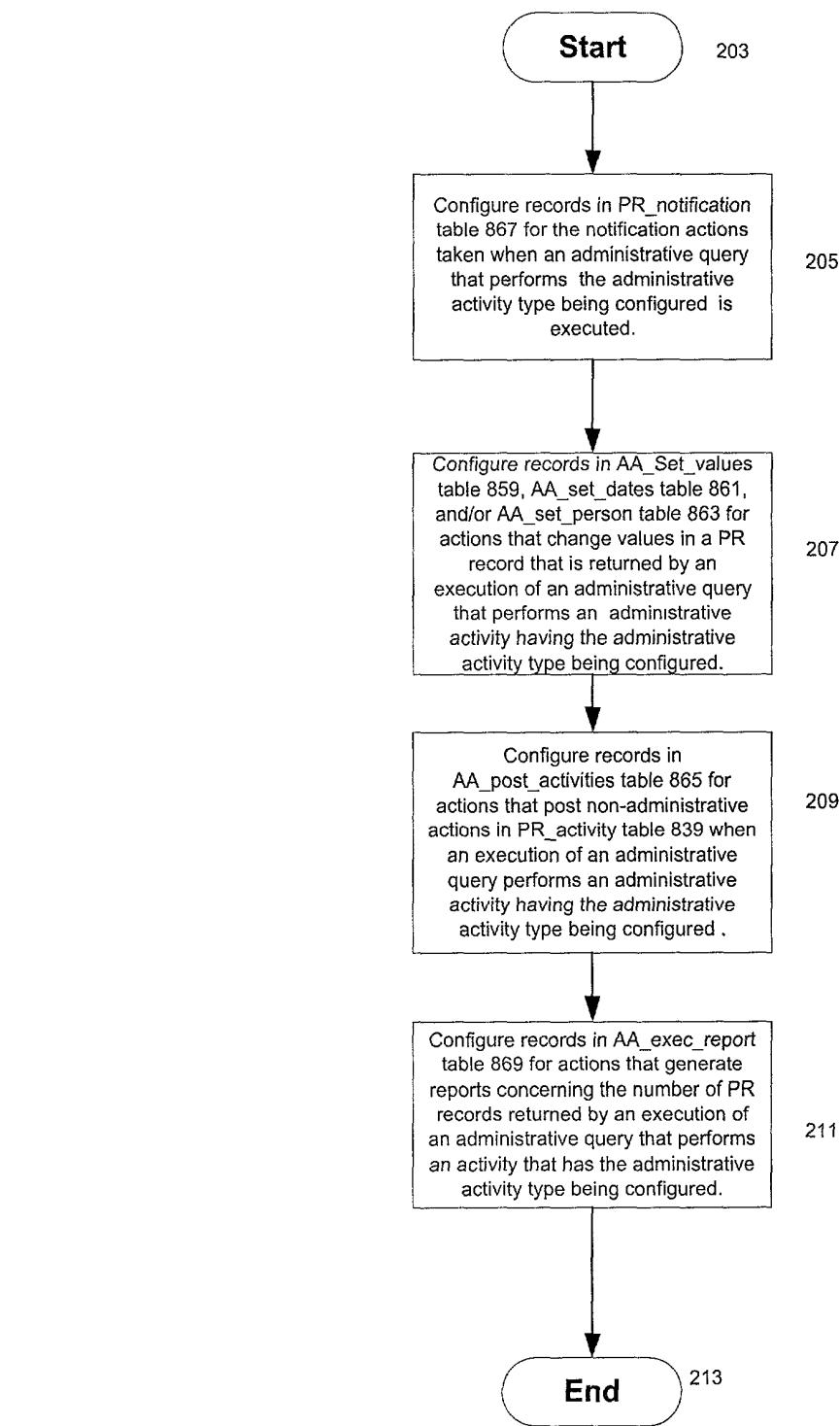
**119:** Upon detection of changes in the execution and, or the processing plans, the system adopts the new plans and is ready to continue with the next cycle



**105:** In this step the next Admin Query, if any, is executed, querying the database, searching for records meeting the given Admin Query conditions.

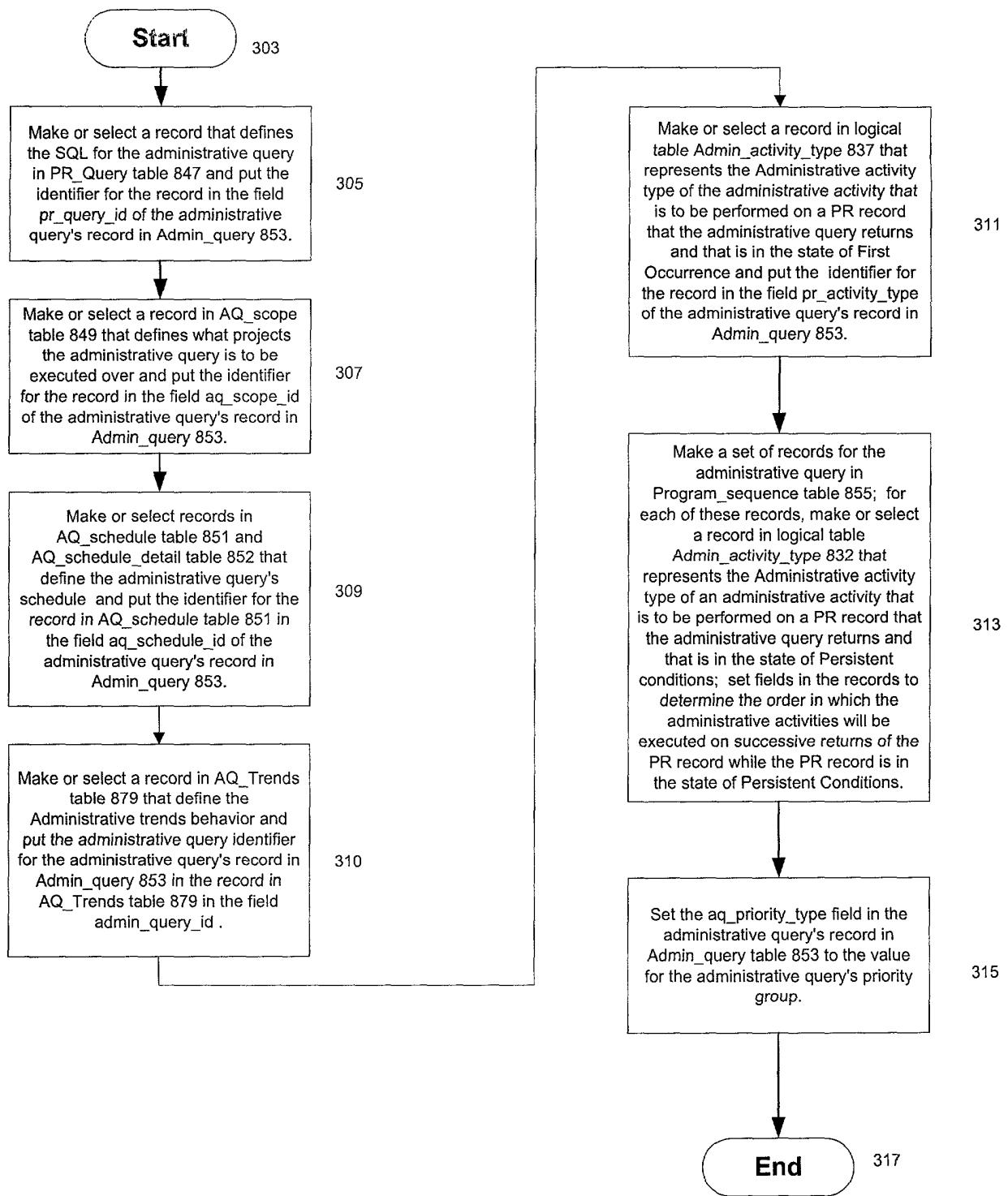
**115:** A periodical check for whether the current execution plan and process plan have changed, e.g.,

- Removal of exiting AQs.
- Changes in Admin Schedule.
- Changes in Admin Scope (adding or removing Projects, i.e., work areas).
- New Admin Activities.
- New Notification Rules.



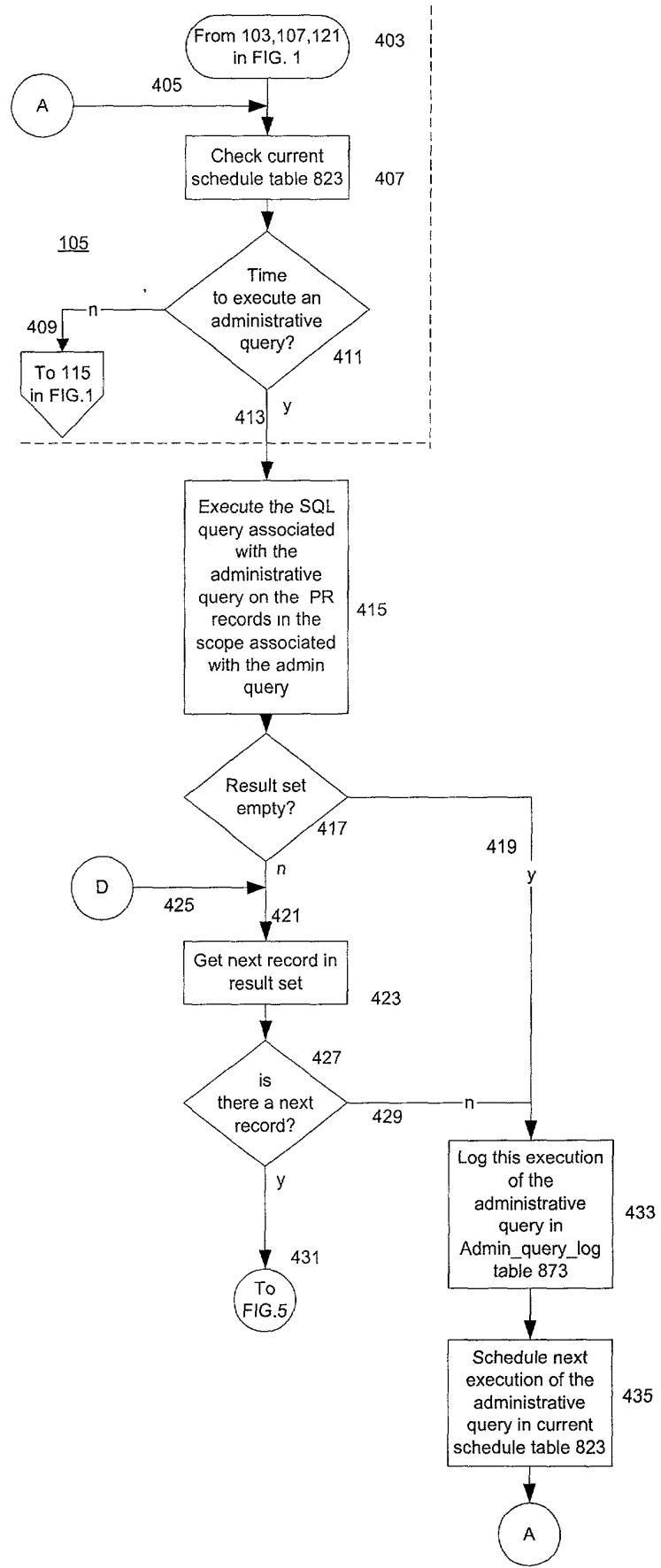
201

**FIG. 2**



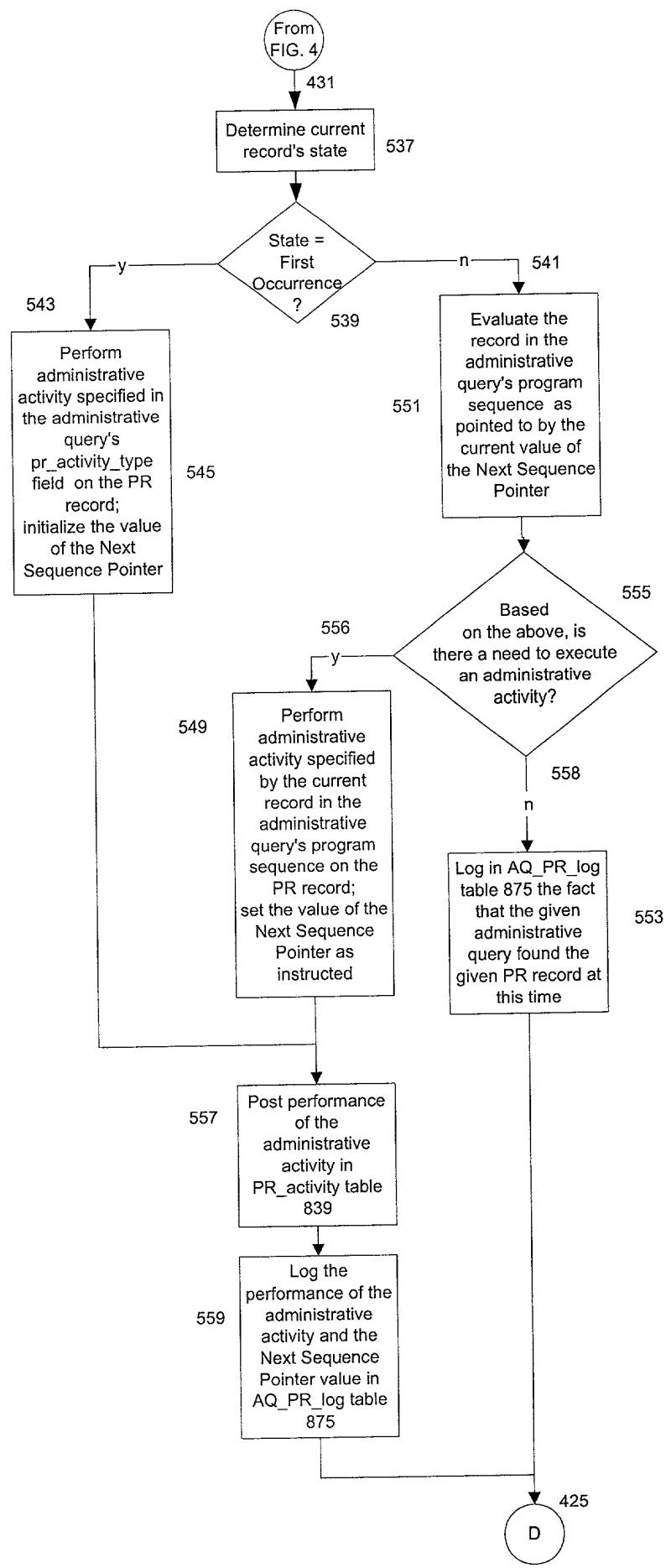
301

FIG. 3



401

**FIG. 4**



501

**FIG. 5**

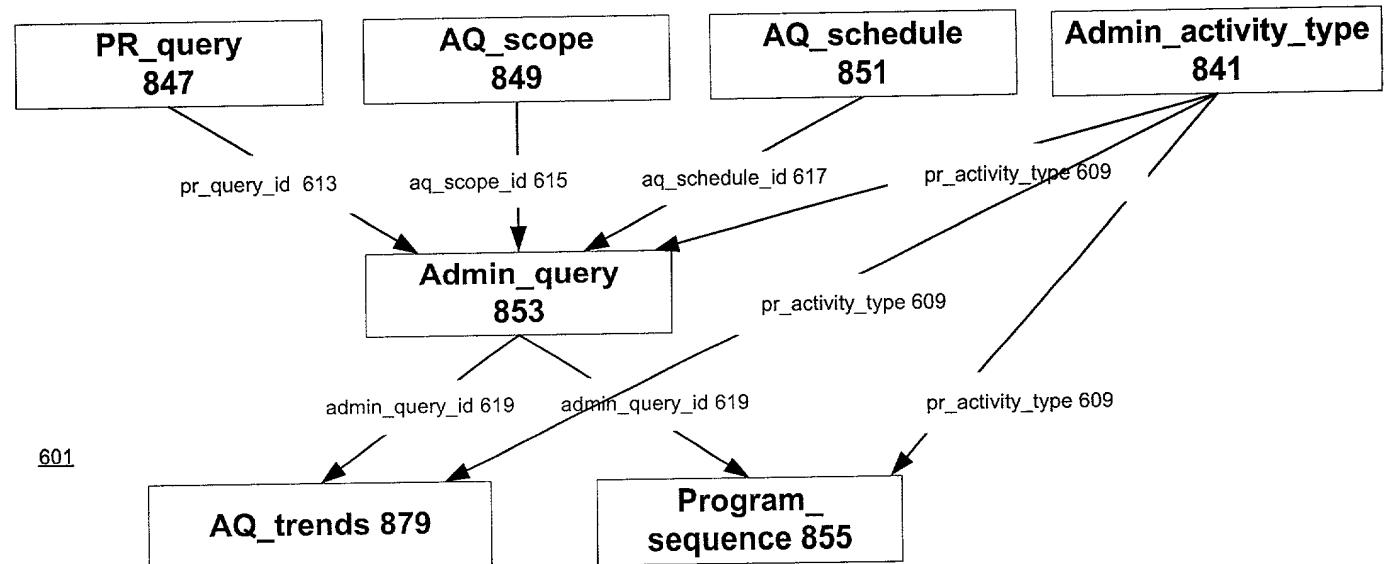
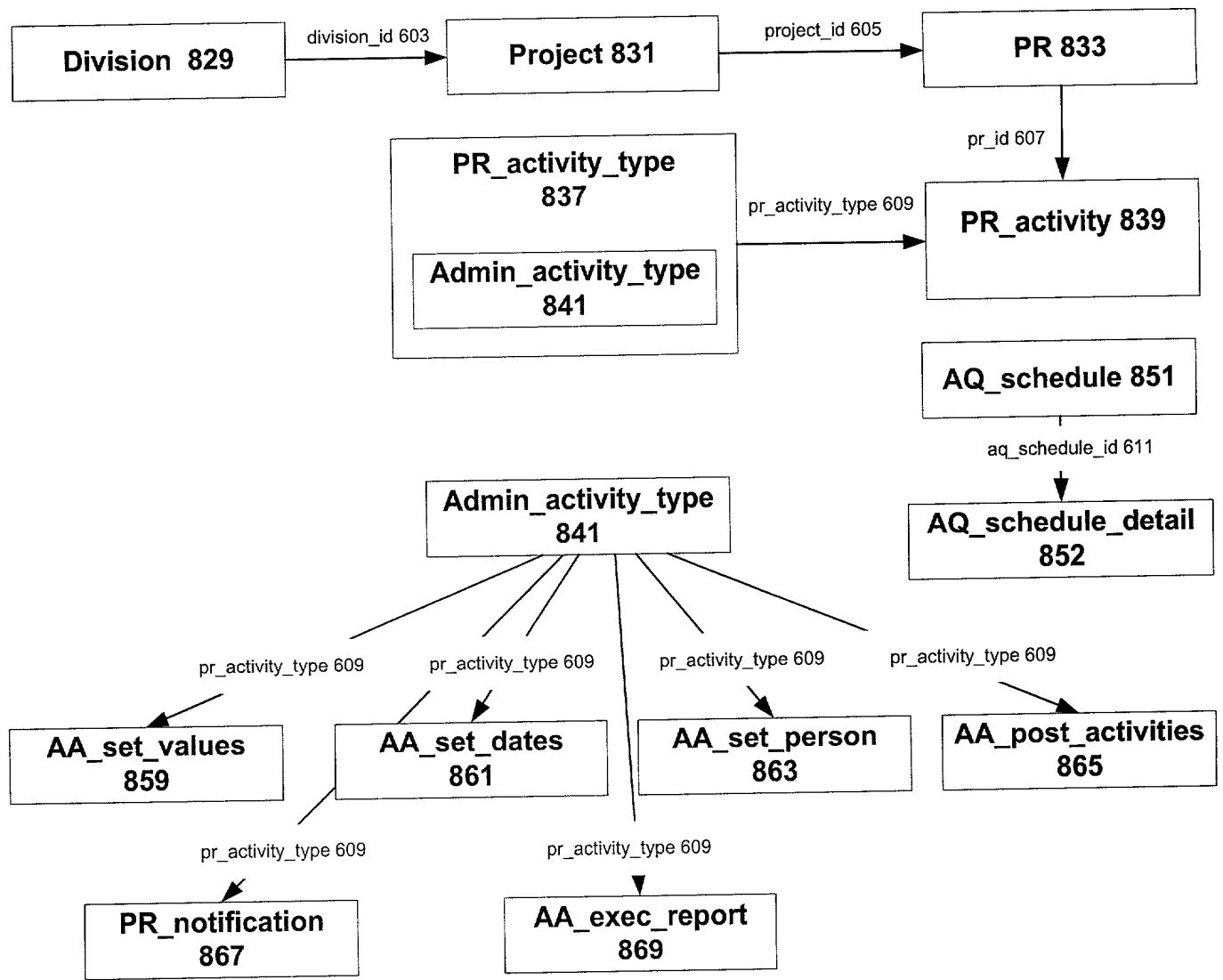
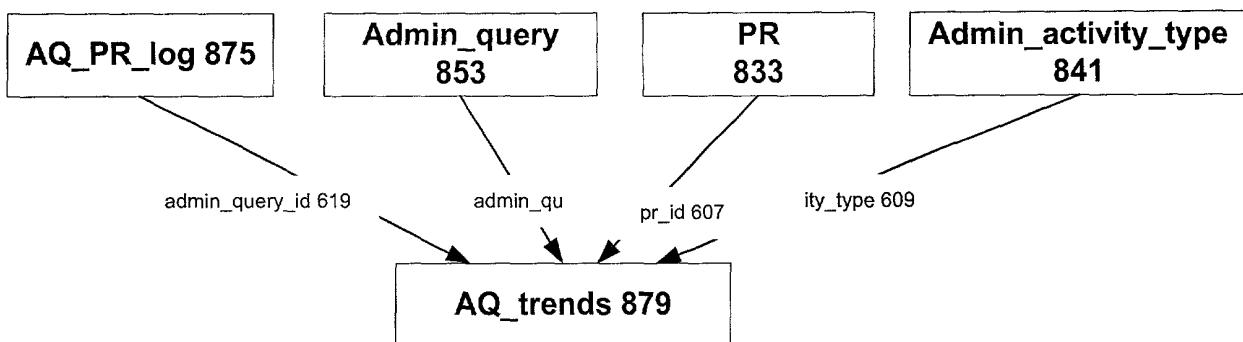
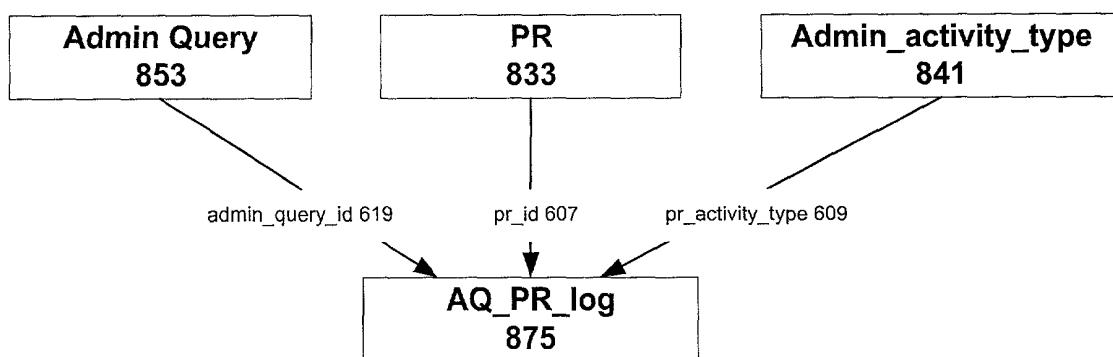
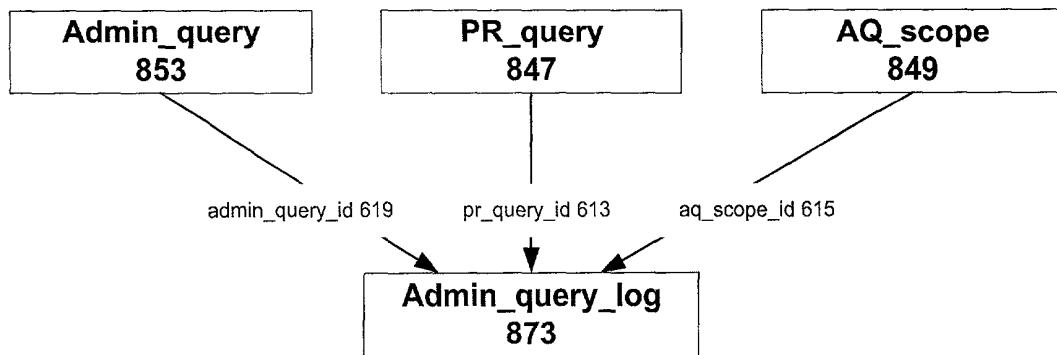
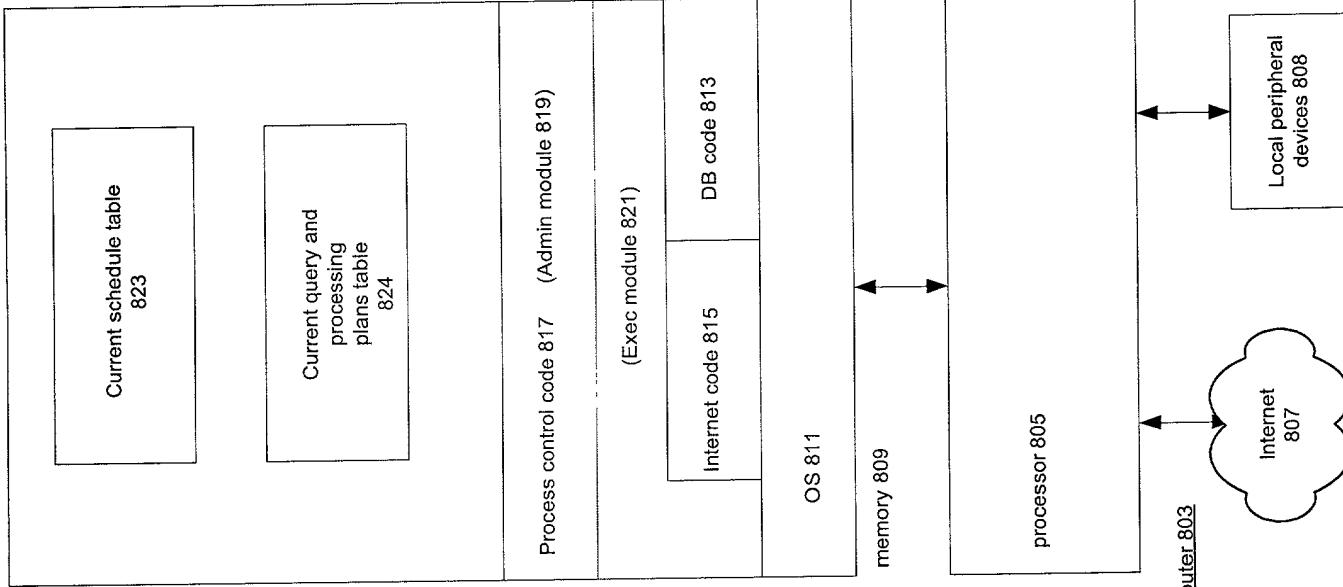


FIG. 6





**FIG. 8**

Current schedule table 823

Current query and processing plans table 824

Process control code 817 (Admin module 819)

(Exec module 821)

Internet code 815 DB code 813

OS 811  
memory 809

processor 805

Local peripheral devices 808

801

DB system 825

Current schedule table 823

Division 829	Project 831	PR 833
--------------	-------------	--------

PR tables 827

PR 847	AQ_scope 849	AQ_schedule 851	AQ_detail 852	AQ_Trends 879	Admin_query 863	Program_sequence 855
--------	--------------	-----------------	---------------	---------------	-----------------	----------------------

Administrative query tables 845

AA_set_values 859	AA_set_dates 861	AA_set_person 863	AA_post_activities 865	PR_notification 867	AA_exec_report 869
-------------------	------------------	-------------------	------------------------	---------------------	--------------------

Action tables 857

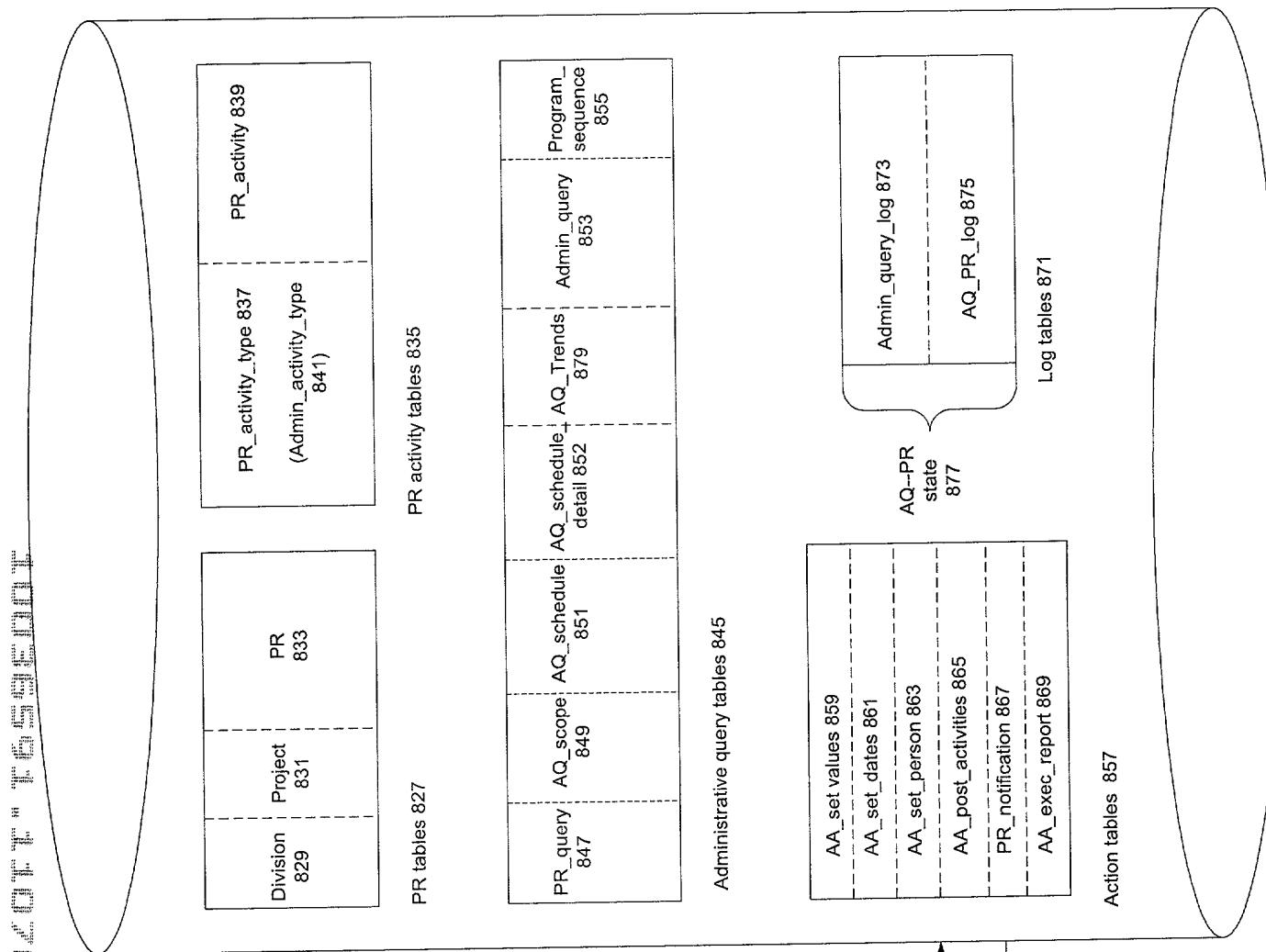
Log tables 871

Admin_query_log 873	AQ_PR_log 875
---------------------	---------------

AQ-PR state 877

PR activity tables 835

PR_activity_type 837 (Admin_activity_type 841)	PR_activity 839
--	-----------------



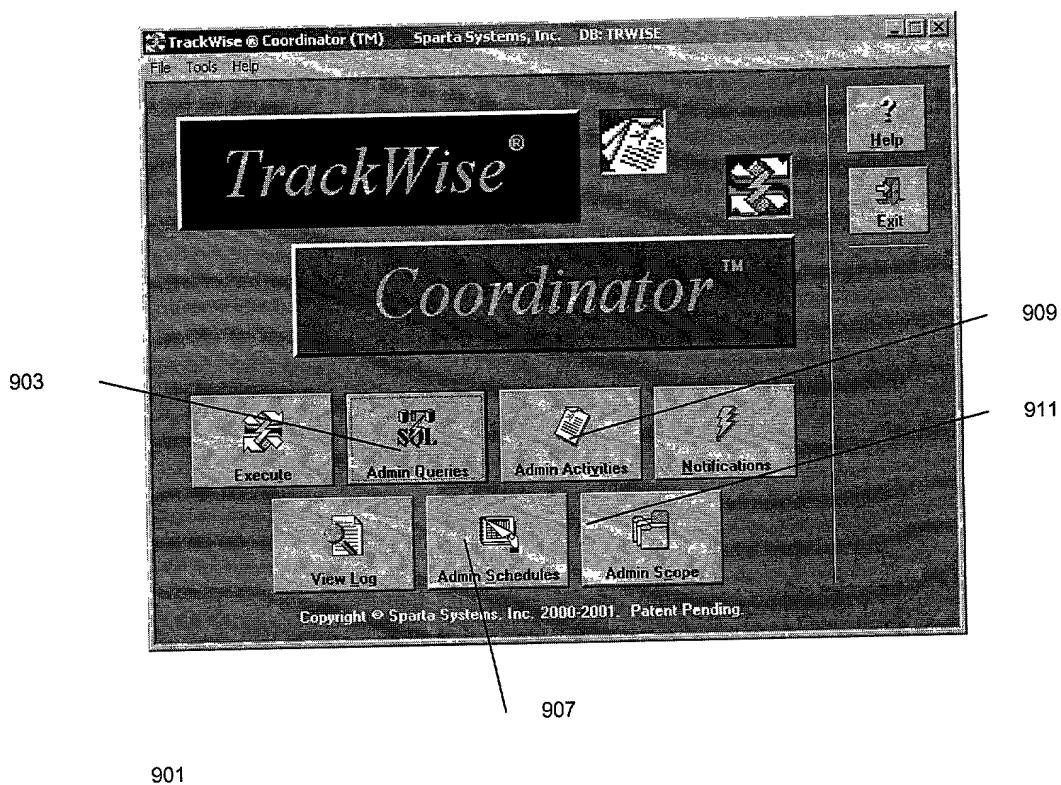
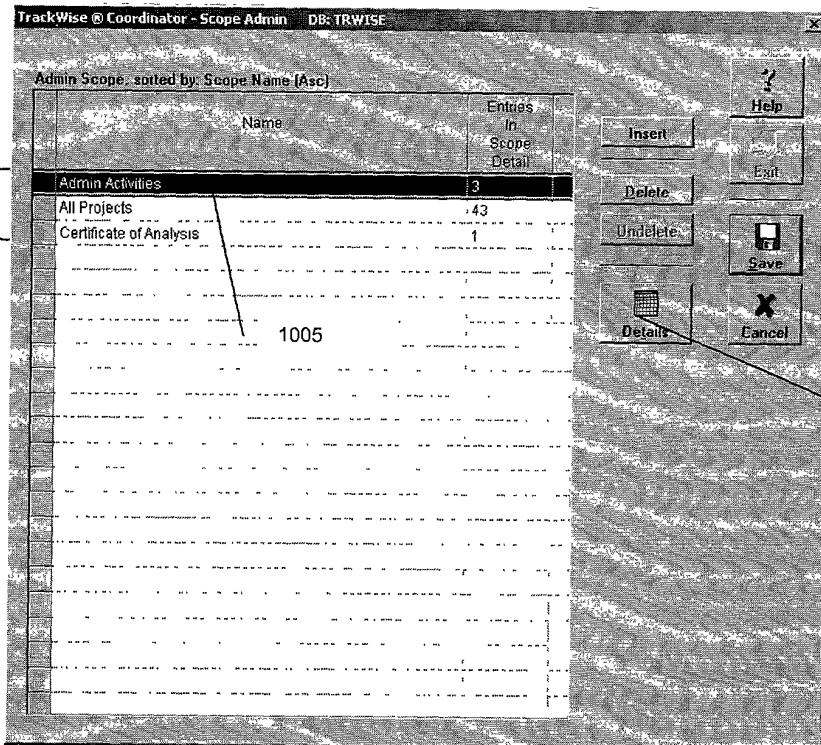


FIG. 9



1001

TrackWise ® - Admin Scope Details DB: TRWISE

Admin Scope: Admin Activities

Scope, sorted by: Included in Scope (Desc)

Department	Record Type	Included In Scope
CAPA - New Jersey	Action Item	<input checked="" type="checkbox"/>
CAPA - California	Action Item	<input checked="" type="checkbox"/>
CAPA - Ireland	Action Item	<input checked="" type="checkbox"/>
Audits - Ireland	Observation	<input checked="" type="checkbox"/>
Audits - California	Audit	<input checked="" type="checkbox"/>
Audits - New Jersey	Observation	<input checked="" type="checkbox"/>
Audits - California	Observation	<input checked="" type="checkbox"/>
CAPA - California	Corrective Action	<input checked="" type="checkbox"/>
CAPA - California	Preventive Action	<input checked="" type="checkbox"/>
Audits - New Jersey	Audit	<input checked="" type="checkbox"/>
CAPA - Ireland	Corrective Action	<input checked="" type="checkbox"/>
CAPA - Ireland	Preventive Action	<input checked="" type="checkbox"/>
Audits - Ireland	Audit	<input checked="" type="checkbox"/>
CAPA - New Jersey	Corrective Action	<input checked="" type="checkbox"/>
CAPA - New Jersey	Preventive Action	<input checked="" type="checkbox"/>
Change Control - California	Request	<input checked="" type="checkbox"/>
Change Control - Ireland	Request	<input checked="" type="checkbox"/>
Change Control - New Jersey	Request	<input checked="" type="checkbox"/>
Complaints - California	Complaint	<input checked="" type="checkbox"/>
Complaints - California	Inquiry	<input checked="" type="checkbox"/>
Complaints - Ireland	Complaint	<input checked="" type="checkbox"/>
Complaints - Ireland	Inquiry	<input checked="" type="checkbox"/>

1010

1011

1012

1009

1013

FIG. 10

FIG. 11

FIG. 11 consists of two screenshots of a software application interface.

The top screenshot shows the "TrackWise® Coordinator - Schedule Admin DB: TRWISE" window. The title bar reads "TrackWise® Coordinator - Schedule Admin DB: TRWISE". The main area is titled "Admin Query Schedules, sorted by Schedule Name (Asc)". It displays a table with three columns: "Name", "Entries In Schedule Detail", and "Detail". The table contains three rows:

Name	Entries In Schedule Detail
Every Day, Every Minute	7
Every Day, Once a Day	7
<b>Monday Friday Every Two Hours</b>	<b>5</b>

On the right side of the window are several buttons: Help, Insert, Exit, Delete, Undelete, Edit, and Details. A mouse cursor is hovering over the "Details" button. The window has a "Row Count: 3" at the bottom.

Annotations with numbers are present: "1103" points to the first row of the table; "1105" points to the "Edit" button; "1104" points to the second row of the table; "1101" points to the "Row Count" text; and "1107" points to the "Details" button.

The bottom screenshot shows the "Schedule Details - Monday Friday Every Two Hours DB: TRWISE" window. The title bar reads "Schedule Details - Monday Friday Every Two Hours DB: TRWISE". The main area is titled "Admin Schedule: Monday Friday Every Two Hours". It displays a table titled "Schedule Details:" with four columns: "Day", "Start Time", "End Time", and "Time Interval". The table lists days from Sunday to Saturday with their respective start and end times and time intervals:

Day	Start Time	End Time	Time Interval
Sunday			
Monday	8:00 AM	5:00 PM	120
Tuesday	8:00 AM	5:00 PM	120
Wednesday	8:00 AM	5:00 PM	120
<b>Thursday</b>	<b>8:00 AM</b>	<b>5:00 PM</b>	<b>120</b>
Friday	8:00 AM	5:00 PM	120
Saturday			

On the right side of the window are buttons: Help, Exit, Clear, Copy to All, and Edit. A mouse cursor is hovering over the "Copy to All" button.

Annotations with numbers are present: "1111" points to the "Day" column header; "1109" points to the "Copy to All" button.

FIGURE 12

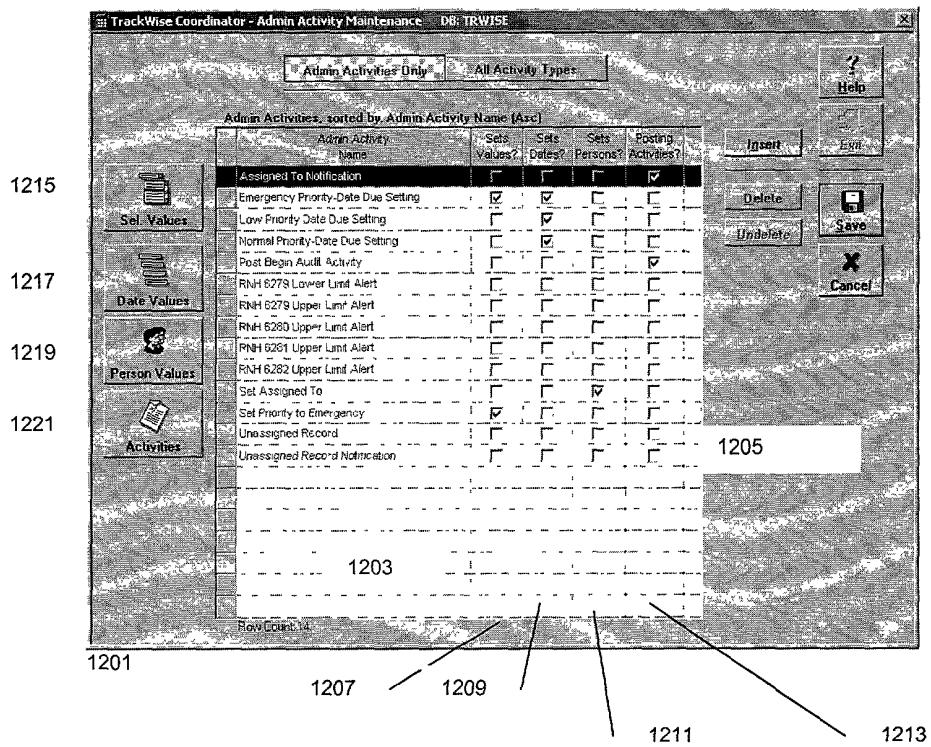


FIG. 12

Administration of Setting Selection Values

Admin Activity: Set Priority to Emergency

Field Name to Set	Field Type	Operation	Set values
Additional Samples Tested?	Selection		
Affected SOP	Selection		
Assessment Method	Selection		
Assignable Cause	Multi-Selection		
Condition	Selection		
Disposition of Samples	Selection		
Final Disposition	Selection		
Governing SOP	Selection		
Impact	Selection		
Location	Selection		
Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection		
Proposed Disposition	Selection		
Type	Selection		

1302      1303      1305      1307      1309

1301      1306

Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	<input checked="" type="checkbox"/> Emergency
Product Family	Selection	Increment	1311
Product(s)	Multi-Selection	Set	
Proposed Disposition	Selection	Clear	
Type	Selection		

1310

1313

Selection Values DB: TRWISE

Emergency
Low
Normal

? Help  
Ok  
Cancel

FIG 13

Administration of Setting Date Values

Admin Activity Assigned To Notification

Field to Set	If Field Is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Analyst Approval On							
Audit Start Date							
Closed On	Date Created						
Date Due	Date Created						
Date Occurred	Date Due						
Director Approval On	Date Occurred						
Discovery Date	Director Approval On						
Next Audit Date	Discovery Date						
QA Approval On	Next Audit Date						
Received Questionnaire	QA Approval On						
Response Due Date	Received Questionnaire						
Sent Questionnaire	Response Due Date						
Supervisor Approved On							

1402

1403      1405      1411      1412

1401      1407      1409      1413

Save      Cancel

1415

Field to Set

Field to Set	If Field Is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Analyst Approval On							
<input checked="" type="checkbox"/> Audit Start Date	Date Created						
Closed On	Date Created						
Date Due	Date Created						
<input checked="" type="checkbox"/> Date Occurred	Date Due						
Director Approval On	Date Occurred						
Discovery Date	Director Approval On						
Next Audit Date	Discovery Date						
QA Approval On	Next Audit Date						
Received Questionnaire	QA Approval On						

1414

1417

1421

1419

1418

Closed On	Date Created	30	Day(s)
<input checked="" type="checkbox"/> Date Due	Date Created	30	Day(s)
Date Occurred			

1424

1422

Closed On	Date Created	30	Day(s)
<input checked="" type="checkbox"/> Date Due	Date Created	30	Day(s)
Date Occurred	Minute(s)		
Director Approval On	Hour(s)		
Discovery Date	Day(s)		
Next Audit Date	Week(s)		

1423

1425

Calendar

FIG. 14

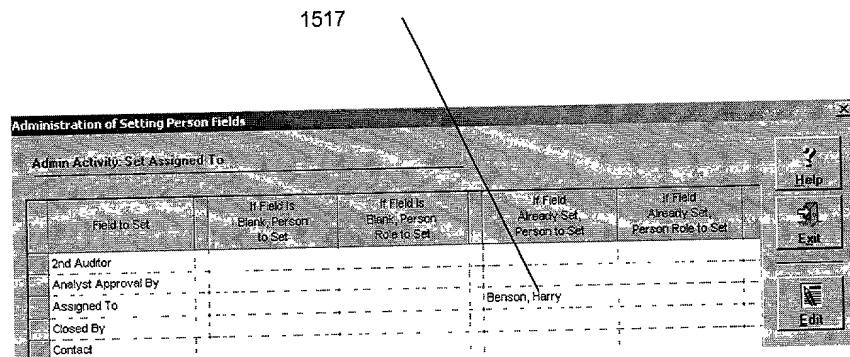
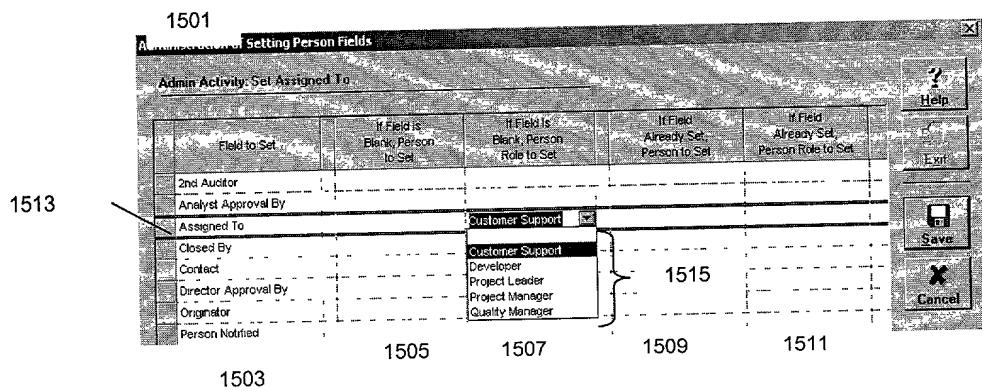


FIG. 15

1602

**Administration of Posting Activities**

**Admin Activity: Post-Begin Audit Activity**

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
<b>Begin Audit</b>	<b>Perform</b>						
Begin Change Control	Schedule						
Begin Investigation	Perform						
*Change Control Cancelled							
Change Request							
<b>Close</b>							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment			1603				
Complete Correspondence			1605				
					1609		
						1611	

Note: Colored-coded activity types require Electronic Signature and can therefore be posted as Scheduled only.

1613

**Administration of Posting Activities**

**Admin Activity: Post-Begin Audit Activity**

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
<b>Begin Audit</b>	<b>Schedule</b>	<b>Current Date/Time</b>	2	<b>Day(s)</b>	<b>Calendar</b>	<b>Contact</b>	
Begin Change Control							
Begin Investigation							
*Change Control Cancelled		1614		1615			
Change Request							
<b>Close</b>							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: Colored-coded activity types require Electronic Signature and can therefore be posted as Scheduled only.

**FIG. 16**

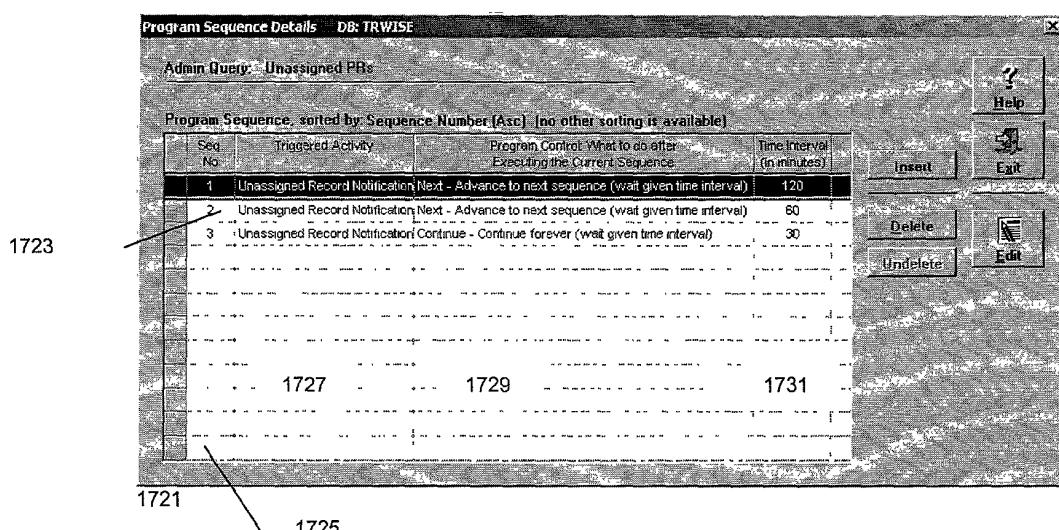
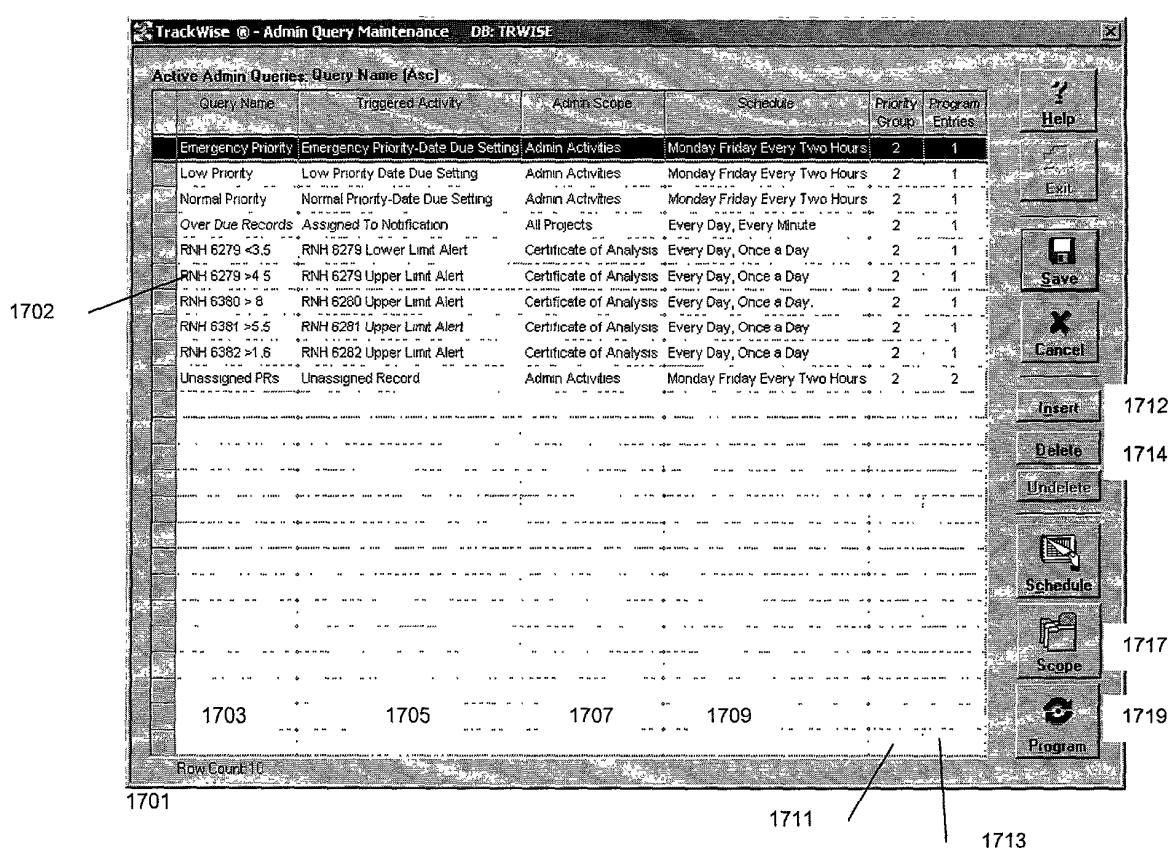


FIG. 17